

y



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/778,548 | 02/07/2001 | David M. Lubman | UM-06102 | 5017 |
| 23535 | 7590 | 07/11/2005 | EXAMINER | |
| MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105 | | | MARSCHEL, ARDIN H | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/778,548

Applicant(s)

LUBMAN ET AL.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18, 20, 26-35, 39-44, 48, 50, 55-58, 73-77, 80-86, & 91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 20, 26-35, 39-44, 48, 50, 55-58, 73, 76, 77, 80-86, & 91 is/are rejected.
- 7) ☒ Claim(s) 74 and 75 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 3/28/05, have been fully considered and they are deemed to be persuasive regarding previous rejections. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Unfortunately, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

The amendment, filed 3/28/05, has been entered. Due to the newly applied rejections summarized below, the finality of the office action, mailed 1/27/05, is hereby withdrawn.

Due to overcoming the previous rejections of record, all of the specie election requirements set forth in the office action, mailed 9/11/03 are hereby withdrawn and all species of the pending claims are now under examination.

NEW MATTER

Claims 1-16, 18, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claim 1 has been amended to cite providing buffer component v) in step a). This buffer is contains a solubilized plurality of proteins but is not written in instant claim 1 as being related to the sample composition as was previously set forth in claim 17. This lack of sample relationship to the buffer is NEW MATTER compared to the

Art Unit: 1631

buffer practice in claim 17. The unrelated sample vs. protein solubilization practice of instant claim 1 has not been found as filed nor pointed to by applicants as to written support as filed and therefore contains NEW MATTER. Claims dependent from claim 1, directly or indirectly also contain this NEW MATTER due to their dependence.

VAGUENESS AND INDEFINITENESS

Claims 1-16, 18, 20, 26-32, 34, 44, and 55-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention..

Claims 26-32, 34, 44, and 55-57 are vague and indefinite as to what limitations are meant therein due to their dependence directly or indirectly from a canceled claim. Clarification via clearer claim wording is requested.

Claim 1, step a), provides items i) - v), which includes a buffer, however, lacks any indication in steps b) through e) as to what cooperativity with the other items in said step a) is required or usage that this buffer is applied to in the method. It is acknowledged that the buffer is described in step a), part v), as being compatible with the first and second separating apparatus which may imply its usage in these apparatus. Such an implication, however, is reasonably not clear and concise thus leaving the buffer usage vague and indefinite. That is, it may be utilized in one or the other of the apparatus or, neither. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 1 also contain this issue.

Art Unit: 1631

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 58 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Opiteck et al. [Anal. Chem. 69:1518 (1997); recently submitted by applicants].

Opiteck et al. discloses an LC/LC/MS system which anticipates instant claim 58. It is summarized therein in the title and abstract and depicted on page 1519 in Figure 1. The first and second separating apparatus elements are shown as the cation exchange column and HPLC column, respectively. The mass spectrometer is operably linked to the second separating apparatus. Two sample handling devices are shown which are valves intermediate between the first and second separating apparatus and between the second separating apparatus and the mass spectrometer. The first sample handling device or valve is reasonably a solid phase device for extraction to waste if desired as a process control treatment of proteins as in part f) of instant claim 58. The automated sample handling device of part b) of instant claim 58 is the other valve sample handler just prior to the mass spectrometer. It is noted that there is no instant definition of what a "solid phase extraction apparatus" is regarding instant claim 58, part f), which distinguishes the solid phase (or valve material) apparatus which extracts proteins to waste as in the reference thus supporting this anticipation rejection. Valves etc. are

Art Unit: 1631

disclosed as being controlled automatically via a Macintosh computer on page 1519, second column, first full paragraph, of the reference as also required in instant claim 58.

OBVIOUSNESS DOUBLE-PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15, 18, 20, 33, 35, 39-43, 48, 50, 73, 76, 77, 80-86, and 91 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 18-35, and 37-47 of copending Application No. 09/968,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a method which is anticipatory as a specie of the claims of said copending application wherein the specie is utilizing the buffer of the instant claims. The remaining first and second separating apparatus and mass spectrometer limitations are shared by the respective claim sets.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

INFORMALITY

The disclosure is objected to because of the following informality:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. The embedded hyperlink is present in the specification on page 34, line 8.

Appropriate correction is required.

CLAIM OBJECTIONS

Claims 74 and 75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 5, 2005

Ardin H. Marschel 7/5/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER